



THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

KALLOO et al

Atty. Ref.: 2784-25

Serial No. 09/815,336

TC/A.U.: 3739

Filed: March 23, 2001

Examiner: Shay, David

For: METHODS AND DEVICES FOR DIAGNOSTIC AND THERAPEUTIC
INTERVENTIONS IN THE PERITONEAL CAVITY

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November 20, 2008

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR §41.41

Sir:

Responsive to the Examiner's Answer mailed September 22, 2008, appellant submits herewith their reply brief pursuant to 37 CFR §41.41.

The method provided in accordance with the invention as defined in claim 1 includes *inter alia* the specific steps of positioning a flexible conduit to extend through a natural orifice, advancing the distal end of the flexible conduit to extend through the wall of the digestive tract, and then anchoring the flexible conduit with respect to the wall of the digestive tract. Thereafter, an endoscope is advanced through the anchored conduit. As noted in the principal Brief on Appeal, Wilk teaches advancing an auxiliary tube through a natural body opening and later advancing an endoscope through the auxiliary tube, but does not teach that the auxiliary tube is passed through an incision, nor that it is anchored to the wall after being passed through the incision. Rather, Wilk teaches that the distal end of the auxiliary tube is brought into fluid-tight engagement with the internal wall of the natural body cavity prior to incising the wall.

In response to appellant's argument that Wilk does not teach advancing "the distal end of his flexible conduit through an incised target wall segment", the Examiner notes that Wilk discloses that the endoscope can be disposed in a sheath, which the Examiner characterizes as constituting a flexible conduit. Even if the sheath is provided as a part of the endoscope in Wilk and that sheath is advanced through the incision, such a sheath does not read on the claimed flexible conduit which is not only advanced through the incised target wall segment but is then anchored to the wall segment and an endoscope is thereafter passed through it. Thus, the Examiner's characterization of the Wilk sheath as the claimed flexible conduit ignores numerous limitations of appellant's independent claim 1.

On page 6 of the Examiner's Answer, the Examiner asserts that, looking at Wilk, "one of ordinary skill in the art" would "readily recognize that" his disclosed components and process are "counterproductive" and that there are problems with Wilk's disclosed product and process and, therefore, the substitution of the sealing method of McNeely for that of Wilk would have been obvious. Appellant respectfully but strongly disagrees with the Examiner's analysis. Indeed, it is respectfully urged that from Wilk's disclosure and/or the McNeely disclosure, the deficiencies of Wilk noted by the Examiner, if in fact they are deficiencies, would not have been readily apparent to the skilled artisan. If they were so obvious, presumably Wilk would have addressed them in the first instance. Quite the contrary, it is only after the Examiner has been given a complete and thorough understanding of the unique and advantageous method and techniques disclosed by appellant that the deficiencies of Wilk are fully appreciated and the significant advantages of the invention thereover are evident. Note in this regard that although the Examiner envisions a variety of problems associated with insufflation in the Wilk's system, McNeely does not provide for any insufflation and, therefore, does not teach or suggest to the skilled artisan that there are problems with Wilk, much less that his gastrostomy catheter would be relevant to the Wilk's process and/or solve

problems related to insufflation. Importantly, McNeely does not even relate to the provision of an auxiliary tube through which endoscopes or other instruments are to be passed. Rather, the tube McNeely anchors relative to the stomach wall is simply a gastrostomy catheter through which nutrients are administered directly to the patient's stomach.

It is respectfully submitted that it is only armed with hindsight knowledge of the unique and advantageous method that appellant has disclosed that the skilled artisan would appreciate the deficiencies of Wilk, the significant improvements taught by appellant, and the advantages of appellant's process over Wilk, and it is only knowledge of appellant's disclosure that motivates the Examiner to select isolated characteristics of McNeely (the paired balloons) and incorporate them in an entirely different surgical procedure wherein there is instrument passage and surgical procedures through an auxiliary tube, as opposed to the administration of nutrients to a convalescing patient. It is respectfully urged that what was complete lacking in the prior art of record is the teaching that there is a structural or method step deficiency in Wilk and how that deficiency might be remedied. The relative simplicity of the structure appellant proposes to use does not detract from its novelty nor the significant advantages made possible thereby, which uniquely distinguish it from Wilk.

With regard to claims 13 and 15, the Examiner notes that the motivation for placement of a balloon on the needle knife conduit is to "reduce the number of steps required to perform the operation, thereby saving time." The Examiner seems to be suggesting that the advantages of the structure proposed by appellant motivate the skilled artisan to implement such changes. However, change cannot be implemented without a teaching or suggestion of that change. In this respect, the novelty of the invention rests in part on the fact that appellant discovered how the number of steps required to perform the operation could be reduced without taking away from its efficacy. Thus, reducing the number of steps might be a motivation to try and invent a

new component for use in the method but it does not teach how the number of steps could be reduced. No doubt there are numerous other incising and dilating systems in the patent prior art, but the fact that dilating systems already exists does not mean that no new dilating systems may now be invented and patented. In the present case, appellant has proposed a new and unique dilating system not taught or suggested in the prior art and having substantial advantages thereover. The advantages of the invention do not motivate the skilled artisan to modify the prior art. Only teachings of how those advantages may be achieved motivate such a change. Such teachings are completely lacking in the prior art applied by the Examiner.

Further, with respect to claims 13 and 15, and also claims 18 and 19, completely lacking in the applied art is the concept of providing a conduit for the needle knife that incorporates a balloon. In this respect, as claimed by appellant, the conduit has the needle knife selectively projectable from it. This allows the needle knife to be concealed until it is immediately proximate the wall segment to be incised. The Examiner's conclusion that it would have been obvious to provide "endoscopic means" such as a conduit for receiving the needle knife is not well taken. In this regard, the needle knife in Wilk could simply be fed through a conduit of the endoscope. This does not teach or in any way suggest, however, a conduit having a balloon on its exterior surface and through which the needle knife is projectable and retractable. Thus, the Examiner's assertion that the combination claimed would have been obvious from Wilk and McNeely ignores the limitations of appellant's claims and does not accurately characterize the options known and available to those skilled in the art. In the absence of a teaching of the unique structure used in the claimed method, it is respectfully submitted that the invention claimed cannot properly be rejected over the applied art.

For the reasons advanced in appellant's Brief on Appeal, and for the reasons advanced hereinabove in supplement thereto, it is respectfully submitted that the

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Examiner's rejections are improper and should not be sustained. Reversal of all rejections of record is respectfully requested.

Respectfully submitted,

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